

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Crossman, Alan, *et al*

SERIAL NO.: 10/527,271

FILED: March 8, 2005

TITLE: TREATMENT OF BASAL GANGLIA-
RELATED MOVEMENT DISORDERS
WITH 2,3-BENZODIAZEPINES

EXAMINER: Javanmard, Sahar

ART UNIT: 1627

CONFIRMATION NO.: 3503

VIA EFS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RULE 132 DECLARATION

Dear Examiner Javanmard,

1. My name is Alan Crossman. I am one of the named inventors in the above-identified patent application.
2. I have been a Professor of Anatomy at the University of Manchester since 1988. My research interest is the functional anatomy of movement disorders. My Curriculum Vitae ("Biographical Sketch") is attached hereto.
3. In preparing to sign this Declaration, I have read the above-referenced application and reviewed the claims in their present form. I understand that claims 26-34, 36, 37, 39-45, and 51 are rejected as obvious in view of Leventer (US 6,649,607) in view of Chenard (EP 0900568 A2).
4. Towards the close of the telephonic Interview of February 10, 2011 concerning the instant application, I agreed to provide a Declaration reiterating certain points I iterated during the Interview.
5. In the first, convulsions and myoclonic tics are very different phenomenologically and pathologically from chorea and dystonia. Convulsions and myoclonus are brief, twitch-like, paroxysmal movements caused by abnormal paroxysmal, spontaneous, explosive discharge of

groups of nerve cells. Such movements often follow stroke or brain anoxia and resemble random jerky twitches.

6. Chorea constitutes squirming, writhing, sinuous movements; dystonia constitutes fixed abnormal postures and contortions of the body. Chorea and dystonia often occur together. They occur in specific types of diseases caused by injury to the basal ganglia.

7. Not only do i) convulsions and myoclonic tics and ii) chorea and dystonia differ phenomenologically and pathologically, they are also treated differently. Indeed, at the time the instant application was filed, there was no FDA-approved drug for the specific treatment of chorea and dystonia. Convulsions and myoclonic tics, however, were known to be treatable using anti-convulsants.

8. At the time of filing, anti-convulsants were not contemplated for treating chorea or dystonia by the person of ordinary skill in the art. In fact, there were publications by pre-eminent scientists in the field of movement disorders indicating that anticonvulsants actually induce chorea and/or dystonia (Chadwick, D., *et al.* 1976 *J Neurol Neurosurg Psychiatry* 39(12):1210-8; and Montenegro, M.A. 1999 *Arq Neuropsiquiatr* 57(2B):356-60). A reading of Chadwick and Montenegro would, in fact, have left me uninclined to treat chorea or dystonia with an agent known to be an anti-convulsant.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 2. February 2011

By: AR Crossman